K062036 1/2

AUG 25 2006

II. Safety and Efficacy Summary

A. *Contact Information*

Patrick Lee
Regulatory Affairs Specialist
Micrus Endovascular Corporation
821 Fox Lane
San Jose, CA 95131

B. *Device Name*

Micrus MicroCoil System, Presidio-18
Device, Artificial Embolization
Regulation Number: 8822.5950
Product Code: HCG
Device Class: II

C. *Predicate Device(s)*

Number	Description	Clearance Date
K053160	Micrus MicroCoil System, Cerecyte-18	Dec 07, 2005
K012145	MicroVention MicroPlex Complex 3D	Oct 29, 2001
K002056	Micrus MicroCoil Delivery System	Jan 11, 2001

D. *Device Description*

The Micrus Presidio 18-System Microcoil consists of an embolic coil ("Microcoil") attached to a Device Positioning Unit (DPU) (single use, sterile).

"Cerecyte" Microcoil Systems in the 18-system size received CE Marking in December 7, 2005. This technical file is in application of CE Marking for the "Presidio" 18-sized system. The Presidio 18-System Microcoil is compatible with commercially available 2-tip marker microcatheters which have internal lumen diameters between 0.017" and 0.021." The coils are available in spherical shapes and are available in various diameters and lengths:

- Coil lengths range from 30 to 50 centimeters.
- Coil diameters range from 8 to 20 millimeters.

Micrus Presidio 18-System Microcoils are fabricated from the same diameter platinum alloy wire as used in the Cerecyte 18 system platinum Microcoils, which is first wound into a primary coil (containing an absorbable polymer suture inside the wind) and then formed into a secondary helical or spherical shape. The Microcoils are subjected to the same thermal treatments for primary and secondary shaping processes. The addition of Presidio 18-System Microcoil to the Cerecyte 18-System line means these 18-System

Microcoils will be identical to the current CE Marked / FDA Cleared Cerecyte 18-System with only a single point of difference (**length**). The platinum alloy wire will match the diameter of all Micrus Microcoil 18 Systems (Platinum only and Cerecyte). The catalog number for Presidio-18 is PC4.

The 18 System Presidio Microcoils maintain the same design features as all the current Micrus Microcoil Systems. Compared with the current design, size 18 Presidio Microcoil Systems have:

- The same intended use
- Connect to the same connecting cables
- Detach using the same Detachment Control Box.

It is important to reiterate, the Micrus Presidio-18 MicroCoils are identical to the current FDA cleared Micrus Cerecyte-18 MicroCoils except for length

E. Intended Use

The Micrus MicroCoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2006

Micrus Endovascular Corporation
% Mr. Patrick Lee
Regulatory Affairs Specialist
821 Fox Lane
San Jose, California 95131

Re: K062036
Trade/Device Name: Micrus Microcoil system "Presidio-18" Model #s: PC4
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG
Dated: July 17, 2006
Received: July 19, 2006

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062036

Indications for Use

510(k) Number (if known): K062036

Device Name: Micrus Microcoil system "Presidio-18" Model #s: PC4

Indications For Use:

The Micrus MicroCoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bye MD for MKM

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062036